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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,554	07/02/2001	Alan R. Tall	64077/JPW/ADM	2853

7590 04/30/2002

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EXAMINER	
LI, RUIXIANG	
ART UNIT	PAPER NUMBER
1646	7

DATE MAILED: 04/30/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/898,554	TALL ET AL.	
	Examiner	Art Unit	
	Ruixiang Li	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5,9-12,15,18-21,23 and 25-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2, 5, 9-12,15,18-21,23,and 25-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 5, and 10-12, drawn to nucleic acids, a vector, a host cell, and a method for producing a polypeptide, classified in class 536, subclasses 23.5, and 24.3; class 435, subclass 320.1, 325, and 69.1.

II. Claim 9, drawn to polypeptides, classified in class 530, subclass 350.

III. Claims 15, 18-20, drawn to an agent, a composition comprising an agent, and a method of preparing such a composition, classification depends upon the structure of the agent.

IV. Claim 21, drawn to a method of inhibiting the activity of a mammalian LOX-1 receptor, classified in class 435, subclass 7.1.

V. Claim 23, drawn to a method of reducing the amount of a mammalian LOX-1 receptor on the surface of a cell, classified in class 435, subclass 6.

VI. Claim 25, drawn to a method of inhibiting the ability of an agent to bind to and activate a membrane-bound mammalian LOX-1 receptor, classified in class 435, subclass 7.1.

VII. Claims 26, 28, and 30, drawn to a method of treating a mammalian subject afflicted with a disorder, classified in class 514, subclass 1.

VIII. Claims 27, 29, and 31, drawn to a method of inhibiting the onset in a mammalian subject of a disorder, in class 514, subclass 1.

2. The inventions are distinct, each from the other for the following reasons. Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instance case, the different inventions are drawn to completely different products having completely different structures and biological functions which are not interchangeable and which require non-cohesive searches and considerations.

3. Inventions IV-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP §806.04, MPEP §808.01). In the instance case the different inventions are drawn to completely different methods each having completely different method steps, using different compositions, and having completely different outcomes. Inventions IV-VI are drawn to a method of inhibiting the activity of a mammalian LOX-1 receptor, a method of reducing the amount of a mammalian LOX-1 receptor on the surface of a cell, and a method of inhibiting the ability of an agent to bind to and activate a membrane-bound mammalian LOX-1 receptor, respectively, whereas Inventions VII and VIII are either drawn to a method of treating a mammalian subject afflicted with a disorder or a method of inhibiting the onset in a mammalian subject of a disorder. These methods are exclusive.

4. Inventions I and V are related as product and process of use. The invention can be shown to be distinct if either or both of the following can be shown: (1) the process

for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05 (h)). In the instance case, the nucleic acid may be used in a materially different process such as to produce polypeptides. For the same reason, Inventions I and VII, Inventions I and VIII are related but distinct inventions.

5. Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05 (h)). In the instance case, the polypeptide may be used in a materially different process such as to immunize mice to produce antibodies. For the same reason, Inventions II and VI, Inventions II and VII, and Inventions II and VIII are related but distinct inventions.

6. Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05 (h)). In the instance case, an agent may be used in a materially different process such as to determine the functions of the LOX-1 receptor. For the same reason, Inventions III and VI, Inventions III and VII, and Inventions III and VIII are related but distinct inventions.

7. Invention I is an independent invention from Inventions IV and VI; Invention II is an independent invention from Invention V; and Invention III is an independent invention from Inventions V. The different inventions are drawn to distinct product and method inventions.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

9. Because these inventions are distinct for the reasons given above and the search required for a single group is not required for any other group, restriction for examination purposes as indicated is proper.

10. Furthermore, the application contains claims drawn to different nucleic acids (SEQ ID NOS: 14, 16, 18, 22, 24, and 26) or amino acids (SEQ ID NOS: 13, 15, 17, 21, 23, 25, 27, and 28). Each individual sequence represents a structural and functionally distinct entity that is capable of supporting a separate patent. The search and consideration of more than a single sequence constitutes an undue search burden on the office, given the ever-increasing size of the database.

Applicant is advised that a reply to this requirement must include an identification of a nucleic acid or an amino acid sequence that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

11. Group VII contains claims directed to patentably distinct species: (a) treating a mammalian subject using an agent that *inhibits the activity* of LOX-1 receptor; (b) treating a mammalian subject using an agent that *inhibits the expression* of LOX-1 receptor; and (c) treating a mammalian subject using a soluble LOX-1 receptor.

12. Group VIII also contains claims directed to patentably distinct species: (a) inhibiting the onset in a mammalian subject of a disorder using an agent that *inhibits the activity* of LOX-1 receptor; (b) inhibiting the onset in a mammalian subject of a disorder using an agent that *inhibits the expression* of LOX-1 receptor; and (c) inhibiting the onset in a mammalian subject of a disorder using a soluble LOX-1 receptor.

Should applicant elect Group VII or Group VIII, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02 (a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published

in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

Ruixiang Li
Examiner
April 20, 2002